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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/120,970	07/22/1998	ROY CURTISS III	53116-1763	2800

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	26

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/120,970	Applicant(s) CURTISS ET AL.	
	Examiner Ginny Portner	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,32,33,35-39 and 41-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *30,32,33,35-39 and 41-65* is/are rejected.

7)☐ Claim(s) *35,52,65* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/26/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 30, 32-33, 35-39,41-65 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 26, 2001 has been entered.

Rejections Withdrawn

1. In view of the new combination of claim limitations, all prior art rejections and the rejection under 35 USC 112, first paragraph are herein withdrawn and new grounds of rejection and objection will be set forth in this Office Action.

Rejections Maintained

1. Claims 43,44-45,47,51,53-55 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting abbreviations that do not clearly define the claimed invention as the meaning of the abbreviations is not structurally, nor functionally defined in the claims. The first appearance of the recited abbreviations should be defined in the claims.

Information Disclosure Statement

2. The information disclosure statement filed October 26, 2001 has been considered.

Response to Arguments

3. Applicant's arguments with respect to claims 30, 32-33, 35-39,41-65 have been considered but are moot in view of the new ground(s) of rejection.

4.

Please Note: The examiner is reading the phrase in independent claim 30

"under the control of an environmentally regulateable control sequence"

to include within its scope a plasmid that comprises a control sequence for expression of the essential gene, wherein upon a change in the external physical environment of the bacterial cell, the plasmid would be lost resulting in the loss of the viability system and bacterial cell death. One such environment would be excretion of the bacterial cell outside the animal, an environment where DAP is not supplemented, thus defining an environment that lacks the selective pressure provided by DAP supplementation, resulting in bacterial cell death.

New Grounds of Objection and Rejection
Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 30, 32-33,35-38, 39, 50-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24 and claims 1-23 (claim 20 defined to include Salmonella) of U.S. Patent No. **6,780,405**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of method of inducing an immunoprotective immune response in a vertebrate anticipates the instantly claimed invention of inducing any type of immune response in an animal, wherein the composition administered in the instant Application comprises a bacteria that may or may not be attenuated, but the allowed species of microorganism must be attenuated (see claim 19), the viability system of the instant Application may be controlled by any number or regulate able control sequences, but the allowed method administers a species which requires specific regulatory sequences (see claims 1-18).

7. Claim 30, 32-33,36-37, 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4, 12 defined to include Salmonella strains of claims 59 of U.S. Patent No. **5,294,441**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of method of stimulating an immune response in an individual anticipates the instantly claimed invention of inducing any type of immune response in an animal, wherein the composition administered in the instant Application comprises a bacteria that may or may not be attenuated,

but the allowed species of microorganism must be attenuated (see '441, claim 4 "avirulent"), the viability system of the instant Application may be controlled by any number or regulate able control sequences, but the allowed method administers a species which recites a specific Asd polypeptide that must be expressed to maintain viability, and if lost due to an environmental condition (see '441, claim 12, paragraph (c), the bacterial cells with lyse (see '441, col. 60, lines 10-12). This reference is also applicable against the claims under 35 USC 102(b) as anticipating the claimed invention.

8. Claim 30, 32-33,36-37, 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 (the Salmonella avirulent strains having been defined to include the strains of claims 5-8) of U.S. Patent No. **5,387,744**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species of method of inducing an immune response in an individual anticipates the instantly claimed invention of inducing any an immune response in an animal, wherein the composition administered in the instant Application comprises a bacteria that may or may not be attenuated, while the strain of '744 must be avirulent (see '744, claim 4 "avirulent"), the viability system of the instant Application may be controlled by any number or regulate able control sequences, but the allowed method administers a species which recites a specific Asd polypeptide that must be expressed to maintain viability, and if lost due to an environmental condition (see '744, claim 8, paragraph (c), the bacterial cells with lyse (see '744, col. 54, lines 19-33). The allowed species of U.S. Patent No. 5,387,744 anticipates the instantly

claimed genus of methods of inducing an immune response. This reference is also applicable against the claims under 35 USC 102(b) as anticipating the claimed invention.

9. Claim 30, 32-33,36-38, 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 (the Salmonella strains being defined to include the strains of claims 5-8) of U.S. Patent No. 5,855,879. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species as the allowed species of method administers a crp mutant strain of Salmonella that lacks a functional chromosomal native asd gene (see col. 58, claim 1 and 8) in a method of stimulating an immune response in an individual. The allowed species anticipates the instantly claimed genus of invention which is directed to a method of inducing any type of immune response in an animal, wherein the composition administered in the instant Application comprises a bacteria that may or may not be attenuated, but the allowed species of microorganism must be attenuated (see '879, claims 1-4, "avirulent"), the viability system of the instant Application may be controlled by any number of regulate able control sequences, but the allowed method administers a species which recites a specific Asd polypeptide that must be expressed to maintain viability, and if lost due to an environmental condition (see '879, claim 8, paragraph (c), the bacterial cells with lyse (see '879, col. 59, lines 1-11). This reference is also applicable against the claims under 35 USC 102(e) as anticipating the claimed invention.

10. Claim 30, 32-33,36-38, 41-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 (the Salmonella strains

being defined to include the strains of claims 5-8) of U.S. Patent No. 5,855,880. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species as the allowed species of method administers a cya mutant strain of Salmonella that lacks a functional chromosomal native asd gene (see col. 54, claims 2 and 7- 8) in a method of stimulating an immune response in an individual.

11. The allowed species anticipates the instantly claimed genus invention which is directed to a method of inducing any type of immune response in an animal, wherein the composition administered in the instant Application comprises a bacteria that may or may not be attenuated, but the allowed species of microorganism must be attenuated (see '880, claims 1-4, "avirulent"), the viability system of the instant Application may be controlled by any number of regulate able control sequences, but the allowed method administers a species which recites a specific Asd polypeptide regulatory system that must be expressed to maintain viability, and if lost due to an environmental condition (see '880, claims 7 and 8 paragraph (c), the bacterial cells will lyse (see '880, col. 54-55, claims 7-8) resulting a lethal effect. This reference is also applicable against the claims under 35 USC 102(e) as anticipating the claimed invention.

Claim Objections

12. Claims 35, 52 and 65 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

13. Claim 35 defines the essential gene and lethal genes to be on an extrachromosomal vector, implying that the scope of claim 30 includes other embodiments, but claim 30 has been amended to recite that the phrase "chromosomal copy of said native gene is inoperable". Claim 30 has been modified to preclude the existence of an operative chromosomal copy of the genes in the Viability system. Thus the genes of claim 30 must be extrachromosomal in order to be operative, and claim 35 broadens the scope of claim 30 by defining the possibility of claim 30 includes operative chromosomal genes.

14. Claim 35 is also objected to for depending from a later number claim 39.

15. Claim 52 also defines the essential gene to be on an extrachromosomal vector thus for the same reasons as recited above for claim 35, broadens the scope of the independent claim from which it indirectly depends. No operative essential genes are chromosomally associated by the newly submitted claim limitations set forth in claim 30, paragraph (iv). The operative essential genes are all-extrachromosomal and would therefore be a nucleic acid vector for expression of the essential gene, a type of extrachromosomal vector.

16. Claim 65 is objected to for depending from claim 31, and is not further limiting of a canceled claim.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 61-64 are rejected under 35 U.S.C. § 112, first paragraph as failing to provide an enabling disclosure.

It is apparent that the claimed extrachromosomal vector comprising pMEG-104 is required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the plasmid vector, see 37 C.F.R. 1.802.

The necessary criteria of the deposit rules under the terms of the Budapest Treaty must be met. An affidavit or declaration by Applicants, or a statement by an attorney of record stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.801-37 CFR 1.809.

19. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 30 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

21. Claim 30 recite the limitation "native gene" and "chromosomal copy" in subparagraph (iv) relative to the essential gene in the Environmentally limited viability system. There is insufficient antecedent basis for this limitation in the claim.

22. Claim 65 depends from a canceled claim and is therefore unclear as to what additional claim limitations are intended to be encompassed by the claim.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
24. Szafranski et al (US Pat. 5,679,533 and US Pat. 5,681,745) is cited to show a lethal gene based extrachromosomal environmentally limited viability system for formulation of vaccine compositions.
25. Hershberger et al (US Pat. 4,436,815; 4,506,013; 4,650,761) are cited to show recombinant host cells that comprise temperature sensitive repressor genes (lambda CI857) and bacteriophage inducible genes (see claims, a lethal gene) that are lethal to the host cells upon induction (see all claims), wherein the host cells also express a heterologous nucleic acid that encodes an antigen (see claim 32).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
January 3, 2005

L. F. Smith

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